

Appl. No. 09/996,555  
Atty. Docket No. 8341  
Amdt. dated July 14, 2003  
Reply to Office Action of March 12, 2003  
Customer No. 27752

Amendments to the Claims:

Claim 1 (currently amended): A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal comprising:

- a. a safe and effective amount of a therapeutically active agent;
- b. an inner coating layer selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:2, poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures thereof; and
- c. an outer coating, applied to the inner coating layer, layer comprising an enteric polymer or film coating material;

wherein the inner coating layer is not the same as the outer coating layer; wherein if the inner coating layer is poly(methacrylic acid, methyl methacrylate) 1:1 then the outer coating layer is not poly(methacrylic acid, methyl methacrylate) 1:2 or is not a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly(methacrylic acid, methyl methacrylate) 1:2; and wherein the inner coating layer and the outer coating layer contain no therapeutically active agent.

*A1*  
Claim 2 (original): The composition of claim 1 wherein the inner coating is poly(methacrylic acid, methyl methacrylate) 1:2.

Claim 3 (currently amended): The composition of claim 1 wherein the outer coating layer is selected from the group consisting of cellulose derivatives, cellulose ethers, methyl cellulose, ethylcellulose, carboxymethylcellulose, carboxymethylethylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, low viscosity hydroxypropyl cellulose, low viscosity hydroxypropyl methylcellulose, wax, or wax-like substance, such as carnauba wax, fatty alcohols, hydrogenated vegetable oils, zein, shellac, sucrose, Arabic gum, polyethylene glycol, polyvinylpyrrolidone, gelatin, sodium alginate, dextrin, psyllium husk powder, polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate (HPMCP), cellulose propionate phthalate, cellulose acetate maleate, polyvinyl alcohol phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), hydroxypropyl methylcellulose hexahydrophthalate, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof.

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Claim 4 (original): The composition of claim 3 wherein the outer coating layer is selected from the group consisting of anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate (HPMCP), cellulose propionate phthalate, cellulose acetate maleate, polyvinyl alcohol phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), hydroxypropyl methylcellulose hexahydrophthalate, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof.

Claim 5 (original): The composition of claim 1 wherein the total coating thickness of the inner and outer coating layers combined is from about 5 mg/cm<sup>2</sup> to about 40 mg/cm<sup>2</sup>.

Claim 6 (original): The composition of claim 5 wherein the total coating thickness is from about 10 mg/cm<sup>2</sup> to about 15 mg/cm<sup>2</sup>.

Claim 7 (original): The composition of claim 6 wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured.

Claim 8 (currently amended): The composition of claim 1 wherein the therapeutically active agent is selected from the group consisting of laxatives, anti-diarrheals, nonsteroidal anti-inflammatory agents, 5-ASA5-aminosalicylic acid, glucocorticoids, antimicrobials, immunosuppressants, chemotherapeutics or anti-cancer drugs, peptides, proteins, cardiovascular drugs, psychotropic drugs, H2-blockers, antiasthmatic agents, and antihistamines.

Claim 9 (original): The composition of claim 8 wherein the therapeutically active agent is a nonsteroidal anti-inflammatory agent.

Claim 10 (currently amended): The composition of claim 9 wherein the therapeutically active agent is 5-ASA5-aminosalicylic acid.

Claim 11 (currently amended): A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal comprising:

- a. a safe and effective amount of a therapeutically active agent;

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- b. an inner coating layer comprising poly(methacrylic acid, methyl methacrylate) 1:2;  
and
- c. an outer coating layer, applied to the inner coating, comprising an enteric polymer or film coating material;  
wherein the inner coating layer is not the same as the outer layer coating.

Claim 12 (currently amendend): The composition of claim 11 wherein the outer coating layer is selected from the group consisting of cellulose derivatives, cellulose ethers, methyl cellulose, ethylcellulose, carboxymethylcellulose, carboxymethylethylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, low viscosity hydroxypropyl cellulose, low viscosity hydroxypropyl methylcellulose, wax, or wax like substance, such as carnauba wax, fatty alcohols, hydrogenated vegetable oils, zein, shellac, sucrose, Arabic gum, polyethylene glycol, polyvinylpyrrolidone, gelatin, sodium alginate, dextrin, psyllium husk powder, polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate (HPMCP), cellulose propionate phthalate, cellulose acetate maleate, polyvinyl alcohol phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), hydroxypropyl methylcellulose hexahydrophthalate, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof.

Claim 13 (original): The composition of claim 12 wherein the outer coating layer is selected from the group consisting of anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, cellulose acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate (HPMCP), cellulose propionate phthalate, cellulose acetate maleate, polyvinyl alcohol phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), hydroxypropyl methylcellulose hexahydrophthalate, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof.

Claim 14 (original): The composition of claim 13 wherein the outer coating is selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:1 and mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

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**Claim 15 (original):** The composition of claim 14 wherein the outer coating is a mixture of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

**Claim 16 (original):** The composition of claim 11 wherein the total coating thickness of the inner and outer coating layers combined is from about 5 mg/cm<sup>2</sup> to about 40 mg/cm<sup>2</sup>.

**Claim 17 (original):** The composition of claim 16 wherein the total coating thickness is from about 10 mg/cm<sup>2</sup> to about 15 mg/cm<sup>2</sup>.

**Claim 18 (original):** The composition of claim 17 wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured.

**Claim 19 (currently amended):** The composition of claim 11 wherein the therapeutically active agent is selected from the group consisting of laxatives, anti-diarrheals, nonsteroidal anti-inflammatory agents, 5-ASAS-aminosalicylic acid, glucocorticoids, antimicrobials, immunosuppressants, chemotherapeutics or anti-cancer drugs, peptides, proteins, cardiovascular drugs, psychotropic drugs, H2-blockers, antiasthmatic agents, and antihistamines.

**Claim 20 (original):** The composition of claim 19 wherein the therapeutically active agent is a nonsteroidal anti-inflammatory agent.

**Claim 21 (currently amended):** The composition of claim 20 wherein the therapeutically active agent is 5-ASAS-aminosalicylic acid.

**Claim 22 (original):** The composition of claim 11 wherein the solid dosage form is a compressed tablet.

**Claim 23 (currently amended):** A method of consistent and reliable maintaining the desired site-of-delivery and release of a therapeutically active agent to the desired region of delivery by orally administering in the gastrointestinal tract through the oral administration of the composition of claim 1.

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Claim 24 (currently amended): A method of consistent and reliable maintaining the desired site  
of delivery and release of a therapeutically active agent to the desired region of delivery by orally  
administering in the gastrointestinal tract through the oral administration of the composition of  
claim 11.

